PAPER NO. 3

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Richard A. Schwartz Art Unit 121
08/23/78 936,280
Bodo Junge et al

MAILED

FEB 16 1979

Sprung, Felfe, Horn,
Lynch & Kramer
600 Third Avenue
New York, N.Y. 10016

THIS IS A COMMUNICATION FROM THE EXAMINER IN CHARGE OF YOUR APPLICATION. GROUP 120

COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined.

☐ Responsive to communication filed on _____.

☐ This action is made final.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE THREE MONTH(S) ~~DAYS~~ FROM THE DATE OF THIS LETTER.

FAILURE TO RESPOND WITHIN THE PERIOD FOR RESPONSE WILL CAUSE THE APPLICATION TO BECOME ABANDONED. 35 U.S.C. 133

PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited, Form PTO-892.
2. ☐ Notice of Informal Patent Drawing, PTO-948.
3. ☐ Notice of Informal Patent Application, Form PTO-152
4. ☐

PART II SUMMARY OF ACTION

1. ☑ Claims 1-46 are pending in the application.
   Of the above, claims 11-15, 33, 39, 44, 46 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-10, 17-32, 34-38, 40-43, 45 are rejected.
5. ☑ Claims 16 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ The formal drawings filed on _____ are acceptable.
8. ☐ The drawing correction request filed on _____ has been ☐ approved, ☐ disapproved.
9. ☑ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☑ been received, ☐ not been received, ☐ been filed in parent application; serial no. _____ filed on _____.
10. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 OG. 213.
11. ☐ Other

Form PTO-44-84 (rev. 5/78)

Restriction between the following inventions is required, 35 USC 121:

I. Compounds, process of making thereof and pharmaceutical composition and method of use employing said compounds. Claims 1-23, 24-32, 34-38 and 40-43; class 424, subclass 267.

II. Compounds, process of making thereof and animal feedstuff composition employing said compounds. Claims 1-23, 33, 39 and 44; class 426, subclass 635.

The above inventions are independent because they are unconnected in operation, and one does not require the other for its ultimate use. They are distinct because they will support separate patents. In addition, they have acquired a separate status in the art, and will require searches which are not coextensive. Accordingly, restriction for examination purposes is deemed proper.

Pursuant to the practice set forth in 976 O.G. 128 regarding Markush-type claims, an election of a species prior to examination is also required.

Applicants' attorney Mr. Kolodny, in telephone conversations with Examiner Schwartz on January 30, 1979, and February 7, 1979, elected the species of claim 16 and Group I, and preserved the right to traverse.

Accordingly, claims 11-15, 33, 39, 44 and 46 are withdrawn from consideration by the Examiner, as being directed to non-elected inventions; 37 CFR 1.142(b).

Applicants are advised that the reasons for traversal must be made of record in order to preserve the right to petition; 37 CFR 1.144.

Claims 1-10, 17-18, 24-32, 34-38 and 40-43 are rejected as obvious, 35 USC 103, over Ohata et al (Ohata). Ohata discloses the lower homolog of the instantly claimed compounds wherein R_3 is CH_2OH, R_2 is H and R_1 is methyl. One of ordinary skill would expect a secondary amine and its N-methyl counterpart to exhibit like behavior. Accordingly, the instant compounds would be suggested. Ex parte Bluestone, 135 USPQ 199.

Claims 19-23 and 45 are rejected as obvious, 35 USC 103, over Saeki et al (Saeki), House, and March. Saeki discloses the hydrolysis of the analog of compound II (R_1=H) to form nojirimycin (note the conversion of VIII to I). Since the hydrolysis would be unaffected by the nature of the substituent on the exocyclic amino group, the instant process would be suggested to one of ordinary skill. House discloses that the formation of enamines from secondary amines and ketones is conventional. House also discloses that enamines may be reduced. One of ordinary skill would recognize these procedures to be useful for alkylation of secondary amines. March discloses that the alkylation of secondary amines with alkyl halides, sulfates or sulfonates is conventional. Saeki discloses the hydrogenation of nojirimycin after its formation by the hydrolysis of compound VIII. The presence of different groups R_1 would not affect the course

of the hydrogenation. Accordingly, the instant processes would be obvious to one of ordinary skill.

Claims 1-9, 17-32, 34-38, 40-43 and 45 are rejected as failing to comply with the requirements of 35 USC 112, paragraphs 1 and 2. The terms "optionally substituted", "hydrocarbon radical", "aromatic or heterocyclic radical", "bioprecursor", "substituents", "heteroatoms" and "monocyclic, bicyclic or tricyclic radical" lack enablement for all they encompass. The terms should be limited to that which is supported by disclosure. The terms are also vague and indefinite. "Bioprecursor", as defined at page 3, does not call to mind any specific chemical compounds. As such, its meaning is unclear. Claim 1 disagrees in number with respect to the recitations of "A compound" and "trihydroxypiperidines". Composition claims and method claims 24-25, 29, 34-36, 38 and 40-43 should include an intended use and/or an amount of active ingredient. The term "effective amount" is vague and indefinite for failing to state intended function. In re Frederiksen, 102 USPQ 35.

Claims 1-9, 17-32, 34-38, 40-43 and 45 constitute an improper joinder of inventions, as they group together inventions that are patentably distinct and separately classified, and will support separate patents. Ex parte Markush, 1925 C.D. 126, provided for this claim structure where there was an emergency-engendered need, as the substances were "so closely

related that they would not support a series of patents". This is not the case here. Therefore, the instant generic claims constitute an improper joinder of inventions; Ex parte Reid, 105 USPQ 251; In re Winnek, 73 USPQ 225; In re Ruzicka, 66 USPQ 226.

Claim 16 is objected to for dependence on a rejected claim.

RASchwartz:mbs
A/C 703
557-2517
02/09/79

JOHN M. FORD
EXAMINER
GROUP ART UNIT 121